GUIDEWIRE HAVING DEPLOYABLE SHEATHLESS PROTECTIVE FILTER

RELATED APPLICATION

This application claims the benefit of U.S. Provisional Application No. 60/437,166, filed December 30, 2002, incorporated herein in its entirety by reference.

FIELD OF THE INVENTION

The present invention relates generally to the field of vascular medical devices. More specifically, the present invention relates to a guidewire protective system for use in vascular procedures that produces a deployable convex filter without the use of a sheath.

BACKGROUND OF THE INVENTION

Arterial disease involves damage that happens to the arteries in the body. Diseased vessels can become plugged with thrombus, plaque, or grumous material that may ultimately lead to a condition known as ischemia. Ischemia refers to a substantial reduction or loss of blood flow to the heart muscle or any other tissue that is being supplied by the artery and can lead to permanent damage of the affected region. While arterial disease is most commonly associated with the formation of hard plaque and coronary artery disease in the heart, similar damage can happen to many other vessels in the body, such as the peripheral vessels and cerebral vessels, due to the build up of hard plaque or softer thrombus or grumous material within the lumen of an artery or vein.

A variety of vascular medical devices and procedures have been developed to treat diseased vessels. The current standard procedures include bypass surgery (where a new blood vessel is grafted around the narrowed or blocked artery) and several different types of non-surgical interventional vascular medical procedures, including: angioplasty (where a balloon on a catheter is inflated inside the narrowed or blocked portion of the artery in an attempt to push back the plaque or thrombotic material), stenting (where a metal mesh tube is expanded against the narrowed or blocked portion of the artery to hold back the plaque or thrombotic material) and debulking techniques in the form of atheroectomy (where some type of high speed or high power mechanism is used to dislodge the hardened plaque) or thrombectomy (where some type of mechanism or infused fluid is used to dislodge grumous thrombotic material). In each of these vascular medical procedures, a very flexible guidewire is routed through the patient's vascular system to a desired treatment location and then a catheter that includes a device on the distal end, appropriate for the given procedure, is tracked along the guidewire to the treatment location.

Although interventional vascular procedures avoid many of the complications involved in surgery, there is a possibility of complications if some of the plaque, thrombus or other material breaks free and flows downstream in the artery, potentially causing a stroke, a myocardial infarction (heart attack) or other tissue death. One solution to this potential complication is to use some kind of occlusive device or filtering device to block or screen the blood flowing downstream of the treatment location.

The use of a protective device in the form of an occlusive device or filtering device as part of a vascular procedure is becoming more common in debulking procedures performed on heart bypass vessels. Most heart bypass vessels are harvested and transplanted from the

saphenous vein located along the inside of the patient's leg. The saphenous vein is a long, straight vein that has a capacity more than adequate to support the blood flow needs of the heart. Once transplanted, the saphenous vein is subject to arterial disease caused by plaque or thrombotic materials that build up in the grafted arterial lumen. Unfortunately, the standard interventional vascular treatments for debulking are only moderately successful when employed to treat saphenous vein coronary bypass grafts. The complication rate for a standard balloon angioplasty procedure in a saphenous vein coronary bypass graft is higher than in a native vessel with the complications including embolization, "no-reflow" phenomena, and procedural related myocardial infarction. Atheroectomy methods including directional, rotational, and laser devices are also associated with a high degree of embolization resulting in a greater likelihood of infarction. The use of stents for saphenous vein coronary bypass grafts has produced mixed results. Stents provide for less restenosis, but they do not eliminate the risk of embolization and infarction.

In order to overcome the shortcomings of these standard non-surgical interventional treatments in treating saphenous vein coronary bypass graft occlusion, embolic protection methods utilizing a protective device distal to the lesion have been developed. The protective device is typically a filter or a balloon. Use of a protective device in conjunction with an atheroectomy or thrombectomy device is intended to prevent emboli from migrating beyond the protective device and allow the embolic particles to be removed, thereby subsequently reducing the risk of myocardial infarction. When the protective device is a balloon, the balloon is inserted and inflated at a point distal to the treatment site or lesion site. Therapy is then performed at the treatment site and the balloon acts to block all blood flow, which prevents emboli from traveling

beyond the balloon. Following treatment, some form of particle removal device must be used to remove the dislodged emboli prior to balloon deflation. U.S. Patent No. 5,843,022 uses a balloon to occlude the vessel distal to a lesion or blockage site. The occlusion is treated with a high pressure water jet, and the fluid and entrained emboli are subsequently removed via an extraction tube. U.S. Patent No. 6,135,991 describes the use of a balloon to occlude the vessel allowing blood flow and pressure to prevent the migration of emboli proximally from the treatment device. While effective as a protective device, balloons may result in damaged tissue due to lack of blood flow downstream of the treatment area due to the time required to inflate and deflate the balloon.

To overcome this disadvantage, most development in relation to occlusive devices has focused on devices that screen the blood through a filter arrangement. An early arterial filtering system utilizing a balloon catheter with a strainer device is described in U.S. Patent No. 4,873,978. The device is inserted into a vessel downstream of the treatment site. The strainer responds to actuation of a separately introduced control cable to open and close a plurality of tines capable of retaining dislodged particles. After treatment, the strainer is collapsed and the entrapped emboli are removed from the body. The additional wire, however, creates additional complexity for the user.

More recently, filter designs have been deployed through the use of a single guidewire in which the filter device is transported to the deployment area within a sheath or catheter. Typical filters have either an umbrella shape to capture emboli or a tube shape in which the proximal end contains larger openings than the distal end so as to allow the blood and debris to enter the filter. The filter thus presents an operational face to the flow of blood within the vessel as provided by

the distal end of the tubular filter that is concave in orientation. Particles are captured within the concave face of the filter and are then retracted out of the vessel when the entire device is removed from the body.

One of the challenges regarding filters is the manner in which it is transported to and from the area of interest. U.S Patents Nos. 6,042,598, 6,361,546, 6,371,970, 6,371,971 and 6,383,206 describe various examples of filter arrangements that are to be deployed through a sheath, while U.S. Patents Nos. 6,080,170, 6,171,328, 6,203,561, 6,364,895, and 6,325,815 describe filters that are deployed by catheter. For example, U.S. Patent No. 6,371,971 describes a blood filter positioned by way of a single guidewire, covered by a sheath for advancement through the channel. The sheath compresses the struts of the filter while in transit. An interventional procedure requires deployment of the sheath along a guidewire down stream of the vascular occlusion. The sheath is retracted and the filter expands to a predetermined size. The filter is retrieved after the procedure by deploying the sheath back down the guidewire, capturing the filter and removing the system from the patient.

The disadvantage associated with this type of filter is the added thickness of the device due to the use of a sheath to deploy the filter. Typical sheath diameters exceed 0.040 inches. Insertion of the sheath can damage the vessel during routing and deployment to the occluded area and during removal. Moreover, the bulky sheath protecting the filter can hamper the debris removal or cause further embolization.

There is a need then for a protective device capable of embolization protection for vascular and arterial procedures without the design limitations of the existing approaches. Occlusive balloons can remain in place too long increasing the risk of vessel damage

downstream of the occlusion. Protective filters avoid this problem but suffer from complicated deployment and retraction schemes. Moreover, existing filters are limited in range due to the filter framework, which also may result in vessel damage. It would be desirable to provide an occlusive filter device easily deployable without a large diameter sheath, along a single guidewire, that reduces the potential for vessel damage.

SUMMARY OF THE INVENTION

The present invention is a guidewire protective system for use in vascular procedures comprising a tubular guidewire, a control cable disposed within the lumen of a guidewire; and a sheathless convex protective filter distally coupled to the control cable and proximally coupled to the guidewire. The filter radially expands as the distal end of the filter is drawn toward the proximal end in response to displacement of the control cable relative to the tubular guidewire. The primary filter action is provided by the outer convex surface of the filter, which is the first surface in contact with the flow of blood within the vessel.

In a preferred embodiment, the filter is comprised of a braided Nitinol wire skeleton frame in the form of a tube to which other fibers are woven to create a filter mesh. In one embodiment, the other fibers are multifilament polymer fibers. In an alternate embodiment, the other fibers are other Nitinol wires of different diameters. A control cable is attached to the distal end of the tubular mesh filter. The proximal end of the control cable extends beyond the proximal end of the tubular guidewire for access. Pulling the proximal end of the control cable draws the distal end of the tubular mesh filter towards the proximal end, which is attached to the guidewire. The filter expands radially until it either fills the vessel or reaches a maximum

expansion point at which filter openings are still smaller than the smallest expected particle size of clinical significance. The filter may be locked in place to prevent premature closure of the filter. In one embodiment, the filter is provided with a radiopaque marker that provides an indication of the position and deployment state of the filter.

Unlike existing filters that have a concave operational surface, the proximal face of the deployed filter of the present invention has a convex shape that provides a first filter surface. Particle removal from the convex surface is preferably accomplished in conjunction with a catheter-based aspiration device, such as a Thrombectomy Device, U.S. Patent No. 5,370,609, commonly referred to as an AngioJet®. The use of an aspiration device enables removal of the majority of particles trapped by the convex face prior to retraction of the filter through an evacuation lumen. Should debris escape the mesh of the convex front surface, the interior distal face of the filter creates a second concave back filter surface which also traps debris. Extraction requires reducing the filter diameter by retracting the Nitinol control cable. The collapsed tubular filter holds debris trapped by the secondary filter surface during the removal process.

In a preferred embodiment, the tubular guidewire is advanced over the control cable in a slidable fashion. A short intermediate tube, disposed between the control cable and the guidewire at the proximal end of the guidewire, provides resistance to the control cable movement. The resistive force maintains the position of the control cable relative the guidewire during a procedure. Alternatively, the filter may be locked into position either by a torque device tightened over the tubular guidewire, or by an interference fit of a feature of the control cable mating with the inner diameter of the tubular guidewire. At the distal end of the control cable, radial expansion of the filter is limited to maintain appropriate maximum allowable mesh

spacing. A stop is crimped on to the control cable beyond the distal end of the tubular guidewire. The crimp blocks control cable advancement into the tubular guidewire at the acceptable limit of deployment. Alternatively, the location at which the proximal end of the filter is joined to the tubular guidewire can be used to control the extent of deployment.

In one embodiment for coronary vascular procedures, the tubular guidewire assembly preferably has an effective length of 190 cm. The diameter of the shaft would be 0.014 inches. Starting profile of the filter is 0.030 inches and fully expanded profile would be 0.3 inches. There is no deployment delay as with inflating a balloon. Deployment is immediate upon activation of the control cable. This embodiment in combination with an aspiration debris removal device is particularly adapted to provide distal embolization protection in debulking vascular interventional procedures, such as those involving a blocked saphenous vein coronary bypass graft. The aspiration debris removal device removes the majority of particles while the filter captures the remainder. Alternatively, the present invention may be configured and sized for use in peripheral vascular procedures or neural vascular procedures.

The advantage of the guidewire protective system of the present invention is that the protective device behaves like an ordinary guidewire yet does not require a bulky sheath for deployment or retrieval. Unlike balloon occlusive devices that block a vessel, the present invention serves as a filter that allows for the continuous flow of blood thus decreasing potential damage to downstage tissue. Unlike other filters, the present invention has a variable diameter based on the extent of deployment which further results in a range of filtration capabilities. Moreover, the flexible nature of the filter mesh conforms to vessel shape and the "soft"

multifilament polymer fibers create less damage. There are no complicated mechanical arrangements or valve systems internal or external to the guidewire protective system.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the present invention prior to expansion of the filter assembly.

FIG. 2 is a perspective view of the present invention after expansion of the filter assembly.

FIG. 3 is a close up perspective view of the filter assembly of the present invention prior to expansion.

FIG. 4 is a close up perspective view of the filter assembly of the present invention partially expanded.

FIG. 5 is a close up perspective view of the filter assembly of the present invention at full operational expansion.

FIG. 6 is a close up perspective view of the wire mesh framework of the filter assembly of the present invention.

FIG. 7 is a perspective view of the present invention with a clamp attached.

FIG. 8 is a side view of another embodiment of the present invention.

FIGs. 9A, 9B and 9C are detailed cross-sectional views of the filter of the embodiment shown in FIG. 8.

FIG. 10 is a detailed cross-sectional view of the distal tip of the embodiment shown in FIG. 8.

FIG. 11 is a detailed view of a section of the mesh of one embodiment of the protective filter.

FIG. 12 is a detailed view of the proximal attachment of the protective filter to the tubular guidewire.

FIGs. 13 and 14 are cross-sectional views of pieces of a clamp arrangement for use with one embodiment of the present invention.

FIGs. 15 and 16 are cross sectional views of an interference feature for use with one embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention is a guidewire protective system for use in vascular procedures. The invention includes a tubular guidewire having a proximal end, a distal end and a lumen. A control cable, having a proximal end and a distal end, is disposed in the lumen of the tubular guidewire.

A sheathless protective filter distally coupled to the control cable and proximally coupled to the tubular guidewire expands in response to the displacement of the control cable relative to the guidewire such that the filter presents at least a convex surface to the flow of blood in a blood vessel. In one embodiment, the sheathless protective filter has a distal interior face which provides a secondary filtering surface. The distal interior face presents a concave surface to the flow of blood within a vessel.

The guidewire protection apparatus is preferably provided with a mechanism for resisting displacement of the control cable relative to the tubular guidewire. In one embodiment, an

intermediate shaft is disposed between the tubular guidewire and control cable at the proximal end. The intermediate shaft is crimped to resist movement of the control cable. When the control cable is adjusted it thus remains in place due to the resistance created by the intermediate shaft. In another embodiment, the control cable contains a stop so as to limit displacement. In a further embodiment, a clamping mechanism is used to selectively clamp the control cable along the guidewire. Alternatively, a feature of the control cable may be designed to provide an interference fit with an interior of the lumen of the guidewire.

The sheathless occlusive filter is preferably comprised of a wire mesh that forms a tubular braided framework over which other members are woven to create the filter surface. In one embodiment, the other fibers are multifilament polymer fibers. In an alternate embodiment, the other fibers are other Nitinol wires of different diameters. The wire used for the framework is biocompatible and has material properties consistent with that needed to create a braided structure. For example, Nitinol wire could be used in this application. In an alternate embodiment, the multifilament polymer fibers that create the filter surface could be woven into a fabric and then attached to the wire mesh.

To allow deployment of the guidewire protection system, the control cable is longer and has a smaller diameter than the tubular guidewire. Preferably, the outer diameter of the guidewire is 0.018 inches or less. In addition, the proximal end of the guidewire will be free of any mechanical connections and obstructions so as to function as a conventional exchange guidewire.

The present invention provides a method of preventing plaque, thrombus or other grumous material and debris from flowing downstream during vascular procedures. The method

includes guiding a tubular guidewire into a blood vessel. A protective filter is then positioned proximate a distal end of the guidewire and distal to the region of the blood vessel to be treated. A control cable coaxially disposed within the guidewire is displaced, thus expanding the protective filter to a deployed state which spans the diameter of the blood vessel. The tubular guidewire is clamped at the proximal end so as to prevent unwanted further displacement of the control cable during the vascular procedure. In a preferred embodiment, the tubular guidewire has a diameter of up to 0.018 inches and is made of a Nitinol or comparable material.

A catheter is introduced over the proximal end of the guidewire and advanced to the region of the blood vessel to be treated. A vascular procedure is then performed in the area using the catheter. The present invention may be incorporated with a vascular procedure such as an asymmetric water jet atheroectomy wherein a jet directs a working fluid at a velocity sufficient to generate a stagnation pressure for removal of a ablated deposit debris. The catheter is also used to remove material captured by the convex proximal face of the filter. The control cable is then released from the crimped guidewire thus contracting the filter. The tubular guidewire with filter is then guided out of the blood vessel.

In the preferred method, the protective filter is comprised of a wire mesh over which other members are co-braided to create a barrier to particles. The wire mesh is attached to the distal end of the control cable and proximate end of the guidewire. The wire mesh and other members are selectively spaced so that particles are captured. In one embodiment, the other fibers are multifilament polymer fibers. In an alternate embodiment, the other fibers are other Nitinol wires of different diameters. Preferably, the fibers and wire mesh are spaced to capture particles of at least 250 microns and more preferably down to 100-150 microns. In the

alternative, the multifilament polymer fibers are woven into a fabric and then attached to the wire mesh. Before deployment, the occlusion filter has a closed position in which the wire mesh and multifilament polymer fibers are disposed generally parallel to the control cable so that the present invention can be inserted into a vessel.

The present invention is also a system for filtering emboli from the blood of a patient generally coincident to a vascular procedure. The system includes lumen opening means, debris filtering means and emboli evacuation means. To open the lumen, a catheter with a distal end having one or more orifices from which a working fluid, such as saline under high pressure, is directed in the form of a fluid jet at a deposit within the blood vessel. The jet impacts the deposit longitudinally so as not to damage the blood vessel. The impact dislodges the deposit and creates a plurality of debris particles.

The lumen opening means further includes a tubular member containing a hypo tube. Preferably, the tubular member is used as an evacuation lumen. The lumen further includes one or more high velocity jets directed to strike a portion of the tubular member. The high velocity jet creates a localized low pressure region which draws the debris particles to the jet and subsequently down the exhaust lumen.

The debris filtering means includes a tube shaped filter which is advanced distally of the deposit by a guidewire. The tube shaped filter is comprised of a wire mesh framework over which a plurality of strands are co-braided. The wire mesh framework is radially deployed. The tube shaped filter is fixed at a proximal end to the guidewire and the wire mesh framework is fixed at the distal end to the control cable. In a non-deployed state, the individual elements of the wire mesh framework lie generally parallel to the guidewire.

The tube shaped filter can be selectively deployed so as to radially expand to encompass the diameter of the blood vessel. At a lower deployment limit, no fluid is able to pass through the filter. In a first embodiment, the lower limit for the filter would be 3 mm. Likewise, the tubular filter has an upper limit based on the unoccupied distance between any two of the strands. This unoccupied distance is defined as a pore size. In a first embodiment, the maximum pore size is 0.010 inch in each direction of the opening so that the tube shaped filter would be able to capture particles of 250 microns or greater. Alternatively, the maximum pore size is 0.005 inches so that the filter is able to capture particles of 100-150 microns or greater. In an alternate embodiment, the multifilament fibers are woven into a fabric prior to attaching them to the wire mesh framework.

In one embodiment, the debris capturing means includes two filtering surfaces. First, a proximal convex face of the tube shaped filter blocks the passage of particles immediately downstream of the vascular procedure. A second debris capturing means includes an interior concave filter face at the distal end of the tube shaped filter.

The outer diameter of the tube shaped filter is smaller than the inner diameter of the blood vessel prior to deployment. In a first embodiment, it is envisioned that the tube shaped filter will have an outer diameter of no more than 0.046 inches prior to deployment.

In operation, it is envisioned that emboli evacuation would include removing the displaced emboli from the proximal convex face of the tube shaped filter through the use of the evacuation lumen. The evacuation lumen is attached to a vacuum pump which provides suction at the distal end. In addition, the evacuation lumen may be driven by the fluid jets which create a stagnation pressure upon striking the mouth of the evacuation lumen. Emboli evacuation is

further accomplished due to the interior concave face at the distal end of the tube faced filter catching emboli that are not trapped by the proximal convex face. The filter is contracted and removed from the body upon completion of the procedure. The trapped emboli are maintained within the filter body during the removal procedure.

Referring now to FIGs. 1-2, the overall operation of a guidewire filter protective system 20 in accordance with the present invention will be described. The guidewire filter protective system 20 in accordance with one embodiment includes a guidewire assembly 30, protective filter assembly 50, and a clamp 70.

The guidewire assembly 30 is a tubular member that includes a proximal portion 32 and a distal portion 34. As used in the present invention, the terms proximal and distal will be used with reference to an operator of the device, such that a distal portion 34 of the guidewire assembly 30, for example, is the portion first inserted into a blood vessel and the proximal portion 32 remains exterior to the patient and is therefore closer to the operator of the device.

The guidewire assembly 30 is comprised of a guidewire 36, a control cable 38 and an optional intermediate shaft 40. The guidewire 36 is a tubular member having a proximal end 32, which remains exterior to the patient, and a distal end 34 which in operation is proximate a vessel of the patient.

The control cable 38 is a wire having a proximal end 48 and a distal end 49 slidably disposed within the lumen of guidewire 36. The control cable 38 extends proximally and distally beyond the respective ends of the lumen 36. The total length of control cable 38 is longer than guidewire 36 to provide for the filter assembly 50 at the distal end 34 and a gripping region 46 at

the proximal end 32. Exact length for the respective elements is determined by the required path to reach the occlusive site within the patient.

In a preferred embodiment, a flexible guidewire tip 60 is positioned in a sleeve 62 at the distal end 49 of control cable 38 to assist in deployment of the system 20 through the vessel. In one embodiment, a stop rod 66 is crimped on to proximal end 48 of control cable 38 to prevent the control cable 38 from completely sliding into the lumen of guidewire 36.

In one embodiment, the control cable's 38 travel is restricted by an intermediate shaft 40 disposed within the lumen of guidewire 36 at the proximal end 32. The intermediate shaft 40 is a tubular member with an inner diameter slightly larger than the diameter of control cable 38 and an outer diameter slightly smaller than the inner diameter of guidewire 36. The intermediate shaft 40 increases the resistive effect on the control cable 38 so as to maintain position relative to guidewire 36. A relatively short intermediate shaft 40, of less than one inch, is used to create the resistive effect. The guidewire 36 is crimpable relative to the intermediate shaft 40 as it is presumed a clamping tool 70 may also be utilized to maintain position.

Alternatively, the intermediate shaft 40 could be eliminated and position maintained by crimping the proximal end 32 of the guidewire 36 to the control cable 38, by using a torque device, by the interaction of a feature on the control cable 38 with the interior diameter of the guidewire 36, or simply by maintaining relative position manually. Although the diameter of the control cable 38 could be of any size consistent with effective use of a guidewire, it will be understood that the larger diameter creates a resistive effect on the guidewire 36, or intermediate shaft 40, so as to maintain position relative to said guidewire 36 when force is removed.

A protective filter assembly 50 having a proximal end 52 and a distal end 54 is located at the distal end 34 of guidewire assembly 30. The protective filter assembly 50 is preferably comprised of a wire mesh framework 56 over which a plurality of multifilament polymer fibers 58 are braided. Alternatively, the wire mesh framework 56 may support a mesh of other fibers or wires, such as a Nitinol mesh of wires 58 as shown in FIG. 11. The proximal end 52 of occlusive filter assembly 50 is laser-welded to the distal end 44 of guidewire 36 as shown in FIG. 12, for example, while the distal end 54 of occlusive filter assembly 50 is laser-welded to the distal end 49 of control cable 38. In one embodiment, a control cable stop 68 is disposed on control cable 38, between the proximal end 52 and distal end 54 of filter assembly 50, so as to limit the travel of control cable 38. Exact location of the stop 68 is determined by the filter spacing created upon radial expansion of the wire mesh framework 56 as compared to the particle size to be filtered.

The individual wire elements 64 of wire mesh framework 56 are disposed parallel to guidewire 36 at the point of attachment so as to present a minimal crossing profile. Individual monofilament polymer fibers 58 are co-braided about the wire mesh 56 to increase cross-section coverage without the stiffness associated with the wires 64. Alternatively, the members 58 may be comprised of smaller diameter wires that exhibit more flexibility than the wires associated with the framework 64. In one embodiment, the filter assembly 50 may be coated with a hemocompatible compound to minimize shear activation of platelets.

During interventional procedures involving carotid arteries and saphenous vein bypass grafts, embolic particles may be liberated causing adverse complications if preventive means are not in place. In a preferred embodiment, as illustrated in FIGs. 1-6, the guidewire filter

occlusion system 20 provides embolic protection. In one embodiment, the tubular guidewire 36 is formed of a Nitinol shaft having an outer diameter of 0.014 inches, an inner diameter of 0.010 inches and a length of 180 cm. In an alternate embodiment as shown in FIGs. 8-10, the tubular guidewire 36 is formed of a braided polyimide tube having an outer diameter of 0.015 inches, an inner diameter of 0.011 inches and a length of 180 cm, such as available from MedSource Technologies, Trenton, Georgia. In one embodiment, the control cable 38, is formed of a Nitinol rod having a diameter of 0.008 inches and a length of 190 cm. In an alternate embodiment, the control cable 38 is formed of a Teflon® coated stainless steel rod having a diameter of 0.095 inches. The control cable core 38 is disposed coaxially with the guidewire 36. Although the length of the guidewire 36 could be any length, it will be understood that it will be shorter than the length of control cable 38. In a first embodiment, the control cable 38 will be at a minimum of 10 cm longer so as to provide for the attachment of the filter assembly 50 at the distal portion 34 and a gripping area 46 at the proximal portion 32. In one embodiment, intermediate shaft 40, is also preferably made of Nitinol with a length of 0.05 inches.

As shown in FIG. 1, the guidewire tip 60 is disposed at the distal end 34 of the guidewire assembly 30. The guidewire tip 60 is preferably a platinum coil with a stainless steel core having a maximum diameter of 0.018 inches and a length of 1.0 inch. Attachment of guidewire tip 60 is accomplished in one embodiment by a stainless steel sleeve 62 that is laser-welded to control cable core 38. A crimp is applied to the sleeve 62 to hold the tip 60 in place. FIG. 10 shows an alternate embodiment of the construction of the guidewire tip 60 where the tip core is fabricated as part of the control rod.

In one embodiment, at the proximal end 48 of control cable 38, a cable stop rod 68 is attached. In this embodiment, cable stop rod 68 is 0.25 inches long with a diameter of 0.014 inches, which is equal to the diameter of guidewire 36. The cable stop rod 68 is crimped on to control cable 38.

In an alternate embodiment as shown in FIGs. 13 and 14, a hemeostatis-like clamp arrangement 80 is utilized on the proximal end 48 of guidewire assembly 20 to secure the control cable 38 relative to the tubular guidewire 30. The clamp arrangement 80 preferably consists of an actuator assembly 82 that is secured to the tubular guidewire 30 and an indicator assembly 84 that clamps onto the control cable 38 by rotation of a knob member 86 that pinches control cable 38 in a wedge structure 88. In one embodiment, the distal end of actuator assembly 82 is provided with structure 90 that attaches the actuator assembly 82 to the guidewire by a torque device, such as a collet clamp. Preferably, both the actuator assembly 82 and the indicator assembly 84 have mated threads 92 that permit the actuator assembly 82 to threadably receive the indicator assembly 84. The indicator assembly 84 preferably includes visible markings at 94 that indicate to an operator the extent of the deployed state of the filter device 50 based on the number of turns of knob 86 as the indicator assembly 84 is unscrewed and control cable 38 is displaced relative to the tubular guidewire 30. It will be understood that alternative arrangements for securing the control cable 38 and tubular guidewire 30 can be used with the indicator assembly such as a pin vise or bearing arrangment, and that a latch, ratchet or other step wise mechanical interface could be utilized in place of the threads 82.

In another embodiment as shown in FIGS. 15 and 16 features an interference fit between a proximal end 48 of control cable 38 and a proximal end 32 of tubular guidewire 30 that

effectively locks the protective filter assembly 50 into a minimum diameter or undeployed state during insertion of the guidewire assembly. This feature is particularly useful to insure that the filter assembly 50 remains in as unobtrusive a state as possible during passage of the distal tip 34 of the guidewire through lesions or tortuous areas of the vessel undergoing a vascular procedure. In interference feature 96 on the control cable 38 frictionally interfaces with the proximal opening of the lumen of the tubular guidewire 30 to secure the relative position between the two. In this embodiment, the interference feature 96 is a frusto-conical shaped member that extends beyond the outer diameter of the control cable 38. Numerous other shapes and configurations such as a lipped configuration or a ratchet arrangement could also be used.

Filter assembly 50 is comprised of a plurality of filter wires 64, which form a framework 56 to support a plurality of polymer strands 58 as illustrated in FIG. 6. In a first embodiment, the polymer strands 58 are co-braided around the wire mesh framework 56. The wires 64 are made of Nitinol, a super-elastic nickel titanium alloy, which is the preferred material because it is easy to braid and biocompatible. A plurality of laser-welds are applied at the distal filter end 52 and proximal filter end 54 to hold the ends of filter wire 64 in position and prevent fraying. At least two welds are performed on each wire 64 at each end so as to hold the wire 64 as small as possible, thus presenting a minimal profile in that deployment without a sheath. Alternatively, adhesive bonds or mechanical interconnections may be used in place of or in addition to welding to secure the filter assembly 50. In an alternate embodiment as shown in FIGS. 11 and 12, the strands 58 are also comprised of Nitinol wire having a smaller diameter (e.g. 0.008") than the wires 64 (e.g., 0.012").

It is expected that the radial expansion of the filter assembly 50 will have an upper and lower limit based on blood flow requirements at the lower limit and the ability to stop particles of an expected size at the upper limit. In a first embodiment, the lower limit of expansion would provide filtration in vessels as narrow as 3 mm. In order to filter particles of 250 microns or larger, the maximum allowable mesh gap would be 0.01 inches which corresponds to a maximum deployment diameter of 0.3 inches. In the closed position, as depicted in FIG. 3, the maximum diameter of the non-deployed filter 50 is 0.038 inches.

In another embodiment as shown in FIGs. 8-12, the filter assembly is designed to filter particles down to a size of between 100-150 microns. The inter-mesh spacings required for such a filtration effect range between 0.004 inches and 0.008 inches as can be seen in FIG. 12, for example. In this embodiment, the expansion size of the filter assembly 50 in a deployed state is selected among a plurality of sizes (e.g., 2-4 mm diameter vessels, 4-6 mm diameter vessels, 6-8 mm diameter vessels) to control the filtration effect of a given sized filter by providing a known range of diameters in the deployed state for which the inter-mesh spacings necessary to achieve the desired filtration effect can then be chosen. In tests with the filter assembly of the present invention deployed within a 6.2 mm acrylic tube, polymer particles of know size were introduced into a fluid flow simulating blood to determine the effectiveness of the filter assembly. When particles of a size of 200 microns were used in this test, 100% of the particles were trapped by the first convex filter of the filter assembly. When the particle size was reduced to 157 microns, 50% of the particles were trapped by the first convex filter, 40% were trapped by the second concave filter and approximately 10% of the particles flowed through the protective device. It will be seen that the sizes of the inter-spacing pores may be adjusted if protection for

smaller size particles is desired to improve the effectiveness of the protective device for particles at those smaller sizes while potentially reducing the flow of blood due to the use of the smaller size pores.

To limit radial expansion of filter assembly 50, in one embodiment control cable stop 68 is coaxially disposed on control cable 38 between the proximal and distal ends of filter assembly 50. Cable stop 68 is a stainless steel tube crimped on to control cable 38 with an outer diameter of 0.012 inches, which stops the control cable 38 from traveling into the lumen of guidewire 36.

The wires 58 and strands 60 lie generally parallel to control cable core 38 when inserted in a vessel. As control cable core 38 is proximally extended, distal filter end 52 is drawn toward stationary proximal filter end 54. Initial displacement, as depicted in FIG. 4, for example, creates a narrow tube as the filter wires expand radially in an elastic manner to form a thin tube. As the control cable core 38 is further displaced, the filter wires 58 continue their radially expansion, as depicted in FIG. 5, until reaching stop 62 or filling the vessel.

It will be understood that the weave of filter assembly 50 may be varied in a number of ways including: change the number of filaments per strand of polymer fiber; change the diameter of the polymer filaments; change the number of Nitinol strands which form the wire mesh skeleton; change the diameter of Nitinol strands; and change the design of the tubular weave. A further advantage to this design is the "softness" created by the polymer fibers as they interact with the blood vessel. Varying the Nitinol strands has a direct effect on the stiffness of the filter and the "softness." However, the Nitinol strand number must be sufficient to adequately constrain the multifilament polymer fibers. Clearly, the options described above may

be used to tighten or relax the weave of the filter. Furthermore, the options may be combined to achieve comparable results.

In practice, medical personnel gain access to the blood vessel lumen through which the guidewire assembly 20 will travel. The guidewire filter protective system 20 is removed from biocompatible packaging. Guidewire tip 60 is inserted into the lumen and is manipulated to a point beyond the vessel occlusion. The control cable 38 is drawn distally from the tubular guidewire 36 so as to radially deploy the filter 50 within the lumen. A rapid exchange device, such as a stent catheter or thrombectomy device, is then deployed on the tubular guidewire 36 with the filter assembly 50 in a deployed state. As illustrated in FIG. 7, a clamp 70 is then applied to the guidewire assembly 20 to maintain the deployed position of the filter 50 until completion of the procedure.

In a preferred embodiment of the present invention, the guidewire protective system 20 is utilized as the guidewire for an atheroectomy or thrombectomy procedure of the type described in U.S. Patents Nos. 5,370,609 or 5,496,267, the disclosure of each of which is hereby incorporated by reference. In each of these embodiments, the guidewire protective system 20 is introduced into the patient, the filter 50 is radially deployed, and then the atheroectomy or thrombectomy catheter arrangement is slid over the proximal end 32 of the guidewire assembly 30 and advanced until it is proximate and proximal to the location of the filter assembly 50. Unlike other occlusive methods, the time period of the procedure is not constrained by concern over blockage of the vessel. The radial expansion of filter assembly 50 allows for the continual flow of blood through the spacing between individual polymer fibers 58. Thus, filter assembly

50 is preferable where ischemia is intolerable or further blood cessation would be irreparably damaging.

Preferably, an evacuation of any debris or other plaque material dislodged in the therapy is accomplished by the evacuation lumen incorporated within the catheter assembly of the above-referenced patents. However, should debris or plaque escape the evacuation lumen the convex proximal face 72 of the filter assembly 50 provides the primary means for trapping this detritus. The concave interior face 74 of the filter assembly 50 provides a second filtering surface. Additionally, a sponge could be compressed to fit within the collapsed filter assembly. Upon deployment, the sponge would provide a third level of filtering. After completion of the procedure the filter assembly is returned to an undeployed state and the guidewire assembly 20 and filter assembly 50 are retracted.

The present invention may be embodied in other specific forms without departing from the essential attributes thereof; therefore, the illustrated embodiments should be considered in all respects as illustrative and not restrictive, reference being made to the appended claims rather than to the foregoing description to indicate the scope of the invention.